REMARKS

This amendment serves as the submission accompanying Applicants' Request for Continued Examination (RCE) filed pursuant to 37 C.F.R. § 1.114. Reconsideration of this application in view of the above amendments and following remarks is respectfully requested.

Claims 1-112 are currently pending. Claims 7-9, 11-12, 15-16, 22-74, 76-83, 100-101 and 103-104 have been previously withdrawn. Claims 13, 76-83 (previously withdrawn), 85-86 and 105 are being canceled. Claims 1, 84, 89-93, 106 and 110 are being amended. Claims 127-129 are new. Support for the amendments and the new claims can be found, for example, on page 112, lines 14-31, page 113, lines 1-14 and Examples 13-25. No new matter is being introduced. Upon entry of these amendments, claims 1-12, 14-75, 84, 87-104, 106-112 and 127-129 will be pending.

The specification has been amended to correct informalities. The corrections are typographical in nature and self-explanatory. No new matter is being introduced.

Claim Rejections Under 35 USC § 102

Claims 1-6, 10, 75, 84-99, 102 and 105-112 have been rejected by the Examiner as anticipated by Wallace et al. (U.S. 6,312,725).

Wallace does not disclose the invention of claim 1, as amended. Amended claim 1 recites a biocompatible gel-forming drug-delivering composition including a drug; a first component comprising at least one sulfhydryl group-containing compound in a liquid medium having an alkaline pH, wherein said sulfhydryl group-containing compound is given by the formula $Core_1$-$(SH)_m$, wherein $m \geq 2$; a second component comprising at least one sulfhydryl reactive group-containing compound in either a liquid medium having a neutral or acidic pH or in powder form, wherein said sulfhydryl reactive group-containing compound is given by the formula $Core_2$-Y_n, wherein Y is a sulfhydryl reactive group and wherein $n \geq 2$; wherein the biocompatible gel-forming drug-delivering composition further comprises a secondary carrier, the secondary carrier being polymeric microspheres that incorporate the drug, wherein the drug is hydrophobic; and wherein at least one of the first or second components is a polyalkylene oxide and wherein the sulfhydryl groups and the sulfhydryl reactive groups react with one

another to form covalent bonds therebetween when said components are mixed together to form a gel in less than one minute.

Firstly, Wallace does not disclose a hydrophobic drug. Instead, Wallace discloses generically a "biologically active substance" that can be present in a hydrogel. Wallace does not, however, mention any solubility characteristics of these "biologically active substance." Secondly, Wallace does not disclose a secondary carrier in addition to the hydrogel, the secondary carrier being polymeric microspheres that incorporate the hydrophobic drug. The Examiner considers that "secondary carrier" mean a pharmaceutically acceptable solvent, suspending agent or vehicle for delivering a bioactive agent. However, Wallace does not mention "pharmaceutically acceptable solvent", "suspending agent" or "vehicle." The Examiner further refers to the optional constituents of Wallace, which constituents may be blended in the composition. However, none of the optional constituents (*e.g.*, collagen, thrombin, fibrin, cells, genes, DNA, etc.) is in colloidal or particulate form. Unlike the polymeric microspheres of amended claim 1, the optional constituents of Wallace either form covalent bonds with the hydrogel or otherwise become part of the hydrogel matrix itself through physical or ionical associations. Accordingly, Wallace does not anticipate amended claim 1.

Claims 2-6, 20, 75, 87-88 and new claims 127-129 depend on claim 1 and, thus, are not anticipated by Wallace. In addition, amended claim 84 recites an additional element that is not disclosed by Wallace. In particular, claim 84 recites that the drug is in admixture with the secondary carrier to form a drug/secondary carrier combination, which can be further in admixture with the first component. As described in Examples 15-16 of the present application, the hydrophobic drug can be first incorporated in polymeric microspheres, which can then be reconstituted in a buffer solution with a gel-forming component. Wallace does not describe this feature. As discussed herein, the optional constituents of Wallace either form covalent bonds with the hydrogel or become part of the hydrogel matrix. There is no description or suggestion of a drug/optional constituent combination, which can be in admixture with a gel-forming component. Accordingly, claim 84 is not anticipated by Wallace.

For the same reasons discussed herein, independent claims 89-93 and 110, as amended, are also not anticipated by Wallace because Wallace does not describe or suggest a

gel-forming, drug-delivering composition comprising a hydrophobic drug being incorporated in polymeric microspheres. Accordingly, claims 89-93, 100 and their dependent claims are novel over Wallace.

Claim Rejections Under 35 USC § 103

Claims 1-6, 10, 13-14, 17-21, 75, 84-99, 102 and 105-112 have been rejected by the Examiner as unpatentable over Wallace et al. (U.S. 6,312,725) in view of Loomis (U.S. 5,854,382).

Wallace and Loomis do not teach or suggest the invention of amended claim 1 because Loomis does not supply a teaching or suggestion of the feature of claim 1 that is missing from Wallace. In particular, Loomis does not teach or suggest a secondary carrier comprising polymeric microspheres. Instead, Loomis describes a drug-delivery hydrogel formed by crosslinked water-insoluble copolymers. Although Loomis describes that the hydrogel can serve as a carrier for drug delivery, Loomis does not describe any secondary carrier in addition to the hydrogel. Accordingly, claim 1 (as amended), its dependent claims and new claims 127-129 are not obvious in view of Wallace and Loomis.

Similarly, independent claims 89-93 and 110, as amended, are also not obvious in view of Wallace and Loomis because they do not describe or suggest polymeric microspheres that incorporate a hydrophobic drug. Accordingly, claims 89-93, 100 and their dependent claims are not obvious in view of the cited references.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

A good faith effort has been made to place this application in condition for allowance. However, should any further issue require attention prior to allowance, the Examiner is requested to contact the undersigned at (206) 622-4900 to resolve the same.

Respectfully submitted,

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